

Dockets Management Branch (HFA-305)  
Food and Drug Administration,  
5630 Fishers Lane, rm. 1061  
Rockville, MD 20852.

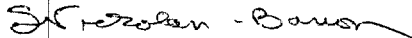
Docket No. 99D-0557

8008 '99 APR 27 A9:17

I would like to make a few comments about this docket number.

- 1) Responsible health authorities would ban all xenotransplants outright, regardless of the species, particularly because of the threats of inter-species virus transmission. (See [www.crt-online.org](http://www.crt-online.org) for other reasons).
- 2) Pigs are being considered as the source animal of choice for xenotransplants. But there is no evidence that pigs are any safer than nonhuman primates. We have plenty of evidence that pig viruses would be just as dangerous as nonhuman primate viruses (i.e. influenza, PERVs, paramyxovirus, and more recently, the Nipah (Hendra-like virus) in Malaysia that has resulted in hundreds of human deaths, and over half a million pigs slaughtered in the last month alone).
- 3) The US should follow Europe's lead. In January 1999, the Council of Europe, representing 40 European countries, recommended a worldwide ban on xenotransplants.
- 4) There are safer and more humane alternatives to xenotransplantation that are not being explored by regulatory authorities. These include aggressively promoting preventive medicine, and increasing human organ donation rates as many European countries have successfully done through various legislative schemes.
- 5) The US General Accounting Office published a report on Organ Donation in April 1998, which revealed an untapped donor pool of 150,000 people in the US. The Department of Health and Human Services should fully investigate the points made in that report before allowing xenotransplants to go forward.

Sincerely



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